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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,858 04/21/99 GHEBRE-SELLASSIE

I 5741-01-E JF

HM12/0209

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EXAMINER

WEBMAN, E

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/284858

Applicant(s)

G H GREE-S CLASSIE

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/23/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1 - 20 is/are pending in the application.
- Of the above claim(s) 11 - 20 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1 - 10 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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Newly submitted claims 10-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant originally elected a composition. Now ne adds a process of making.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9311749 ('749).

'749 teaches troglitazone in a solid dispersion comprising polyvinylpyrrolidone. (See page 9 lines 16-36). Polyethylene glycol is disclosed (Abstract). 5:1 drug: carrier is specified (page 7 line 19). Applicant argues that '749 does not disclose a crystalline active. However, the process in Example 1 is performed at a melting point below that of the drug.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olefsky et al. (U.S. 5,478,852) in view of Grabowski et al.

Olefsky et al. teach troglitazone and <sup>si</sup>troglitazone (column 26 lines 57-59, column 28 lines 10-11). Solid form preparations are specified (column 16 lines 55-60).

Grabowski et al. teach delayed release compositions (column 1 lines 51-55) which are solid compositions comprising an active and a polymer (claim 1). Hydroxypropylcellulose, hydroxypropylmethylcellulose (claim 4) and polyvinylpyrrolidone (claim 5) are disclosed.

The amount of active is as high as 90% (column 3 line 13). Polyethylene glycol is specified (column 3 line 48).

7/15/01  
JA  
Applicants argue that the active can be amorphous. However, <sup>nifedipine</sup>~~nifedipine~~, a crystalline compound, is processed at a temperature below its melting point in example 1. That is, it remains crystalline. Applicant argues that Grabowski et al. teaches two polymers, however, column 2 lines 32-33 and 39 indicate that the polymers (in this case hydroxypropyl cellulose) can be the same, although of different viscosities.

IT WOULD HAVE BEEN OBVIOUS TO ONE OF ORDINARY SKILL TO DERIVE THE COMPOSITION OF OLEFSKY ET AL WITH THE VENUE OF GRABOWSKI ET AL TO ACHIEVE THE BENEFICIAL EFFECT OF CONTROLLED RELEASE.

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The examiner notes that applicant discloses extrusion (page 6 lines 25-28) at temperatures comparable to '749 and Grabowski et al.

No claims allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9:00 a.m. to 5:0 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

E. Webman:jmr

January 17, 2001